UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,563	03/08/2001	Stuart B. Levy	PKZ-043	5356

959 7590 06/18/2002

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER
LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
1648	6

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/801,563	Applicant(s) LEVY ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- Th MAILING DATE of this communication app ars on the cov r sh et with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, and 17-18, drawn to methods of identifying NIMR activity modulators by determining the ability of a test compound to modulate NIMR polypeptide activity, classified in class 436, subclass 501.

II. Claims 11-16, drawn to methods of identifying NIMR expression modulators by determining the ability of a test compound to modulate expression of an NIMR polypeptide, classified in class 436, subclass 501.

III. Claims 19 and 20, drawn to methods of decreasing the virulence of a microbe, or of reducing marA mediated transcription of an NIMR gene, comprising exposing the microbe to an environmental challenge and a modulator of NIMR activity, classified in class 424, subclass 139.1.

IV. Claims 21-29, drawn to methods of identifying NIMR activity modulators by determining the ability of a test compound to bind to an isolated NIMR polynucleotide, classified in class 436, subclass 501.

V. Claim 30, drawn to a vaccine comprising at least one NIMR nucleic acid molecule, classified in class 536, subclass 23.1.

VI. Claim 30, drawn to a vaccine comprising at least one NIMR polypeptide and an acceptable carrier, classified in class 514, subclass 2.

VII. Claims 31 and 32, drawn to compositions comprising a compound that modulates NIMR activity, classified in class 439, subclass 139.1.

VIII. Claim 33, and 36-38 drawn to a method of reducing microbial virulence in a subject by administering at least one NIMR modulator to the subject, classified in class 424, subclass 139.1.

IX. Claim 34, and 36-38 drawn to a method of treating a microbial infection by administering at least one NIMR modulator to the subject, classified in class 424, subclass 139.1.

X. Claim 35-38 drawn to a method of reducing the infectivity of a microbe by contacting the microbe with at least one NIMR modulator, classified in class 424, subclass 139.1.

For Group I above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of groups I-X, and, if group I is elected, to one of inventions (A)- (C). Inventions (A)-(C) comprise the method of Group I, wherein the step of determining comprises:

(A) measuring efflux of test or marker compound from the cell;

(B) measuring the ability of the microbe to grow or remain viable; or

(C) measuring ability of compound to bind NIMR.

For group II above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of groups I-X and, if group II is elected, to one of inventions (D)- (F). Inventions (D)-(F) comprise the method of Group II, wherein the step of determining comprises:

(D) measuring the amount of RNA produced by the cell;

(E) measuring the amount or activity of a reporter gene product produced by the cell; or

(F) measuring that ability of an antibody to bind to the reporter gene product.

For each of groups I, II, and IV above, restriction to one of the following Inventions is also required under 35 USC 121. Therefore, election is required of one of groups I-X and, if

Group I is elected, then election is also required to one of the inventions listed in Group (G);

Group II is elected, then election is also required to one of the inventions listed in Group (H); or

Group IV is elected, then election is also required to one of the inventions listed in Group (I).

Group (G) consists of the 49 NIMR proteins listed in Claims 2 and 6 as filed.
Group (H) consists of the 51 NIMR proteins listed in Claims 12 and 13 as filed.
Group (I) consists of the 51 NIMR proteins listed in Claims 22 and 24 as filed.

The inventions are distinct, each from the others, for the following reasons:

2. Inventions (A)-(F) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate to different methods of identifying NIM modulators. In each of the inventions, the method is carried out by measuring a different occurrence or product. As each of the methods measures something different, they are each using a different mode of operation. The different modes are not discloses as usable together. The inventions are therefore distinct.

3. The inventions listed in Group (G), (H), and (I) are each unrelated to the other inventions listed in the same Group. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions each relate to modulators of different proteins. The target proteins each have different structures, and perform different functions. Therefore, modulators of these different proteins will likewise have different structures and have different effects (they will modulate different protein

functions). Neither the proteins, nor their modulators have been disclosed as usable together. The inventions are therefore distinct.

4. Groups I, II, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate to methods of identifying different NIMR modulators. The modulators of Group I are NIMR activity modulators that bind to NIMR proteins; those of group II are NIMR expression modulators; and the modulators of Groups IV are NIMR activity modulators that bind to NIMR polynucleotides. Group II performs a different function from the other two groups. Groups I and IV each have a different mode of operation (they function by targeting different molecules). As the modulators are not disclosed as usable together, and because they either perform different functions or have different modes of operation, the groups are distinct.

5. Groups III, and VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different groups relate to methods that produce different effects. As each of the methods produces a different effect, and they are not disclosed as usable together, the groups are distinct.

Further, while all of the groups require administration of an NIMR modulator, group III also requires administration of an environmental challenge to a microbe. As none of the other methods require such an administration, this method also has a different mode of operation.

6. Groups VII and IV are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Group IV may be used with several materially different products. See paragraph 3 above (explaining how the inventions listed in Group (G) are different. Group G lists different inventions within Group IV). As the methods of Group IV may be used with any of the materially distinct products of Group VII, it is distinct from all of those inventions.

7. Groups V-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different groups each relate to a different type of molecule. Group V reads on NIMR nucleic acids, Group VI on NIMR polypeptides, and Group VII on NIMR modulators. Each of these molecule types performs a different function. None of them are disclosed as usable together. Therefore, the Groups are distinct.

Conclusion

8. Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

9. Applicant's attention is hereby directed to the following is a recitation of M.P.E.P. §821.04 regarding the restriction of claims to a product and processes of using the product, Rejoinder:

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02© and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.
>
> Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.
>
> In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

> "However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

In accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain

either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
June 5, 2002

JAMES HOUSEL 6/17/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600